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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,725	09/22/2008	Patrick Lewis Blott	SMNPH.009APC	3301

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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11/28/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
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Office Action Summary	Application No. 10/599,725	Applicant(s) BLOTT ET AL.	
	Examiner ILYA TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 21-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/14/2011; 07/14/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1 and 5-15 are amended.
2. Claims 16-36 are new.

Response to Arguments

3. Applicant's arguments filed 07/14/2011 have been fully considered but they are not persuasive:

4. With respect to claim 1, Applicant argues that Freeman does not disclose a fluid moving device applied downstream of and away from the wound dressing.

However, it is clearly depicted on Freeman's fig. 1 that the peristaltic pump that is a fluid moving device is located away from the wound dressing and, consequently, downstream.

5. Applicant further argues that Freeman does not disclose the fluid moving device configured to apply negative pressure to the wound.

However, since Freeman expressly discloses the process of removing the solution from the treated area, the moving device configured to apply negative pressure is necessarily present..

With respect to Applicant's arguments regarding regulator, Applicant's arguments are substantially based on the amendment made to the claim. See rejection below.

Election/Restrictions

6. Newly submitted claims 21-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Art Unit: 3761

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20, drawn to an apparatus for aspirating, irrigating and/or cleansing wounds.

Group II, claim(s) 21-36, drawn to apparatus for aspirating, irrigating and/or cleansing wounds.

Where the group of inventions is claimed in one and the same international application, the requirement for unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "**special technical features**" shall mean those technical features that define a contribution which each of the claimed inventions considered as a whole , **makes over the prior art**. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, although they share the special technical feature, this special technical feature does not define a contribution over the prior art for the following reasons: Claim 1 is either obvious or anticipated by any one of the following US 2003/0021775. Accordingly, the special technical feature linking the inventions, *a regulator in communication with at least one of the inlet passageway and the offtake passageway* does not provide a contribution over the prior art, and no single general inventive concept exists. Therefore the restriction is appropriate.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3761

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-4 and 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 2003/0021775) in view of Lockwood et al. (US 2002/0161346).

11. In Re claims 1-4 and 13-18, with regard to applicant's "means for supplying thermal energy" and "means for providing simultaneous aspiration and irrigation", the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for " or "step for; "

(B) the "means for " or "step for " must be modified by functional language; and

Art Unit: 3761

(C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant met the limitations set forth in MPEP § 2181, since applicant defines the structure of the "means for" within the claim.

Freeman discloses an apparatus for treating the skin surface, comprising:

- (a) a fluid flow path, comprising a conformable wound dressing 24 (page 5, [0074], line 1; fig. 1), having a backing layer which is capable of forming a relatively fluid-tight seal over a wound (page 6, [0074], lines 14-29), an inlet pipe 20 (page 5, [0074], line 5; fig. 1) defining an inlet passageway in communication with a space under the backing layer for connection to a fluid supply tube, which passes under the wound-facing face 28 (page 5, [0074], line 9), an outlet pipe 22 defining an offtake passageway (page 5, [0074], line 6; fig. 1) for connection to a fluid offtake tube, which passes through the wound-facing face 28 forming a relatively fluid-tight seal over the wound;
- (b) a fluid reservoir 10 (page 5, [0074], line 2; fig. 1) in flow communication with the inlet passageway configured to provide irrigant to the wound;
- (c) a device 18 (page 5, [0073], line 12; fig. 1) for moving fluid through the wound dressing;
- (d) a means for supplying thermal energy 14 (page 5, [0071], lines 4-5) to the fluid in the wound, wherein the means for supplying thermal energy may be radiantly or convection-heated chamber, that corresponds with the definition recited in the instant Specification (Spec., page 4, [0090], lines 5-6); and

Art Unit: 3761

(e) a pump that is a means for providing simultaneous aspiration and irrigation of the wound (page 6, [0074], lines 14-18), such that fluid may be supplied to fill the flow path from the fluid reservoir via the fluid supply tube while fluid is aspirated by a device through the fluid offtake tube, that corresponds with the definition recited in the instant Specification (Spec., page 7, [0206], lines 1-5).

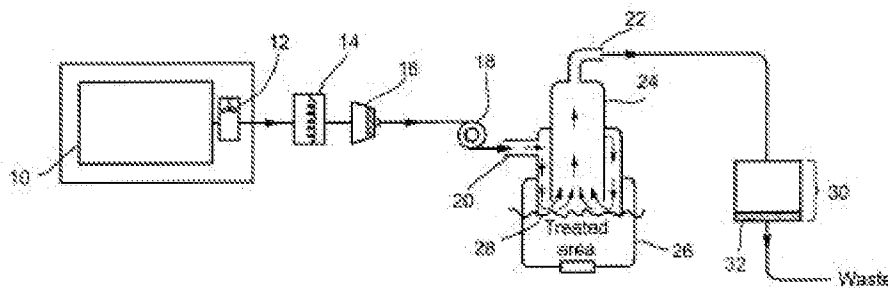


Fig. 1

Freeman does not expressly disclose the apparatus comprising a regulator in communication with at least one of the inlet passageway and the offtake passageway and configured to at least regulate a rate of fluid flowing through at least one of the inlet passageway and the offtake passageway.

Lockwood teaches a wound treatment apparatus comprising a switch valve 66 (fig. 1) that is a regulator coupled to both the inlet passageway and the offtake passageway regulating a rate of fluid flowing through the inlet passageway and the offtake passageway necessarily controlling the speed of the fluid moving device and fully capable of holding negative pressure on the wound at a steady level while simultaneous aspiration and irrigation is provided to the wound (page. 3, [0027]).

Art Unit: 3761

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Freeman with the regulator, as taught by Lockwood in order to allow a user to switch between the use of the vacuum source and the irrigation source, as motivated by Lockwood (page 6, [0087], lines 1-3).

12. In Re claim 12, Freeman discloses the apparatus, wherein the means for supplying thermal energy to the fluid in the wound causes the fluid in the wound to reach temperatures between 30°C and 40°C that encompasses the claimed temperature range.

13. In Re claim 19, Freeman discloses the apparatus, wherein a device for moving fluid is a variable-throughput device (page 5, [0073], line 24).

14. In Re claim 20, Freeman discloses the apparatus, wherein the he means for providing simultaneous aspiration and irrigation of the wound comprises a peristaltic pump (page 5, [0073], line 24).

15. Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 2003/0021775) in view of Lockwood et al. (US 2002/0161346), and further in view of Neher (DE3935818A).

16. In Re claims 5, 7 and 9-10, Freeman discloses the invention discussed above but does not expressly disclose the apparatus comprising a first device for moving fluid to the wound and a second device for moving fluid from the wound.

Neher teaches an apparatus for healing wound (Abstract, line 1), wherein an irrigation solution is supplied by a first pump, and the used solution is removed by a second pump (Abstract, lines 5-8), wherein both pumps are fully capable of being a fixed throughput device.

Art Unit: 3761

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Freeman/ Lockwood with the second pump, as taught by Neher in order to provide separate control over the supplied and removed fluid flows.

17. In Re claim 6, Freeman discloses the apparatus, wherein the aspirated fluid goes to the collection vessel 30 (page 6, [0076], line 1; fig. 1).

18. In Re claims 8 and 11, Freeman discloses the apparatus, wherein a device for moving fluid is a variable-throughput device (page 5, [0073], line 24).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit
3761